IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KATHY SEIFRIED, Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CO., AND MITSUBISHI TANABE PHARMA CORP., Defendants.	CIVIL ACTION NO.: 3:16-cv-01931-BRM-LHG CIVIL ACTION (Document Filed Electronically) **Return Date: September 6, 2016**

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON'S MOTION TO DISMISS

Christopher A. Seeger
Jeffrey Grand (*pro hac vice* pending)
Daniel R. Leathers
Seeger Weiss LLP
550 Broad Street Suite 920
Newark, New Jersey 07102
Telephone: (973) 639-9100
Facsimile: (973) 639-9393
E-mail: cseeger@seegerweiss.com
E-mail: jgrand@seegerweiss.com
E-mail: dleathers@seegerweiss.com

Attorneys for Plaintiff

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

State Cases

State Statutes

Federal Rules

Federal Regulations

Other Authorities

I. INTRODUCTION

Invokana is a name-brand medication prescribed for the treatment of Type 2 diabetes. Plaintiff Kathy Seifried developed diabetic ketoacidosis due to ingestion of Invokana. As a result, she asserts 12 claims against Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson ("J&J"), and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi"). Janssen and J&J ("Defendants") have moved to dismiss Plaintiff's complaint. The Court should deny Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

First, Defendants put the Rule 8 plausibility standard on a pedestal equal to that of a claim sounding in fraud under 9(b). As a result of that unfounded supposition, together with a circumscribed reading of Plaintiff's complaint, Defendants cobble together case law to seek dismissal, citing to numerous (off-point) cases or *generic* pharmaceutical cases in defense of this *brand-name* pharmaceutical drug suit. As generic drugs are subject to different rules than brand-named prescription medications, the cases cited by Defendants are inapplicable here. Applying the correct Rule 8 plausibility standard with on-point case law nets an entirely different result: her claims survive under both New Jersey and Alabama law.[1] Ms. Seifried is entitled to punitive damages under either New Jersey or Alabama law.

Second, Ms. Seifried's design defect-based claims (Counts 2 and 5–7) are not preempted by federal law. Defendants again cherry-pick from limited case law supporting their sweeping contention that all design defect cases against generic **and brand-name** prescription drug manufacturers would be preempted despite binding Supreme Court precedent to the contrary.

Third, Defendants assert that claims against Johnson & Johnson are preempted because

[1] This court need not, at this juncture reach a choice of law analysis because Plaintiff's claims survive under both states' laws. To the extent that the Court may ultimately believe that any of Plaintiff's claims fail under either states' laws, that is a question for another day. *See* Section III, *infra*.

Johnson & Johnson is merely a "holding company" and had no authority to amend the design or labeling for Invokana. This is inaccurate. As demonstrated by judicially-notable materials publicly available from both the FDA and Johnson & Johnson's own website, J&J actively manages Janssen Pharmaceuticals and even shares research and marketing personnel with Janssen. It was and remains intimately involved in the development and labeling of Invokana. Thus, Plaintiff's claims against Johnson & Johnson are not preempted.

II. BACKGROUND

Ms. Seifried began using Invokana to treat her diabetes in 2013 and subsequently experienced diabetic ketoacidosis. *See* Compl. ¶¶ 4, 7, 28, 33, 40-41. Plaintiff alleges that Defendants failed to adequately warn of the risk of diabetic ketoacidosis from ingesting Invokana, along with other injuries that can be caused by the drug, some of which may also result to kidney damage.

But Plaintiff alleges more than the mere use of Invokana in connection with Ms. Seifried's injuries. Plaintiff alleges that Defendants knew the mechanism of action of the sodium-glucose cotransporter 2 inhibitors and that Invokana's mechanism of action results in diabetic ketoacidosis, severe kidney damage, as well as other injuries. *Id*. ¶¶ 18-22. Moreover, Defendants were aware of a growing number of Invokana adverse event reports, yet did not change the label, or otherwise warn physicians, patients, or the public at large of those dangers. *Id.* ¶¶ 23-28, 34-37, 39.

III. CHOICE OF LAW

On a motion to dismiss for failure to state a claim, a "defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In order for Defendants to successfully dispose of ***any*** of Plaintiff's claims, Defendants bear the burden on showing that her claims fail under **both** Alabama and New Jersey law in their

opening brief. Stated another way, because Defendants have failed to make any claim-by-claim arguments required for a choice-of-law analysis – let alone any discussion of conflict at the outset – Defendants bear the burden of proving the claims fail under **both** of the set-forth states (Alabama and New Jersey) for each claim.

In any event, choice of law issues are inappropriate to resolve on a motion to dismiss in the first instance when key factual matters have yet to develop. *See, e.g., Argabright v. Rheem Mfg. Co.*, No. CV 15-5243 (JBS/AMD), 2016 WL 3536621, at *4 (D.N.J. June 28, 2016) (denying a motion to dismiss and simultaneously finding that because "the factual record is not full enough to make a choice of law determination, the Court will postpone the choice of law analysis to a later stage"); *Krys v. Aaron*, 106 F. Supp. 3d 472, 481 (D.N.J. 2015) (stating that "the factual inquiry necessary for a choice of law analysis often proves 'inappropriate or impossible' at the motion to dismiss stage 'when little or no discovery has taken place.'") (quoting *Erlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 700-01 (D.N.J. 2011) (citation omitted) (also citing additional cases that have determined that a choice-of-law analysis is premature at the motion to dismiss stage); *Snyder v. Farnam Co.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (same); *Harper v. LG Elecs. USA, Inc.*, 595 F. Supp. 2d 486, 491 (D.N.J. 2009) (same).

IV. LEGAL STANDARD

A plaintiff's pleading requires "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. at 570). To meet the plausibility standard, a plaintiff's allegations must show that defendant's liability is more than "a sheer possibility." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556

U.S. at 678.

"The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* All a Plaintiff must show are facts that tend to "'raise a right to relief above the speculative level[.]'" *Siwulec v. J.M. Adjustment Servs., LLC,* 465 F. App'x 200, 202 (3d Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, (2007)). "The issue before the Court is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." *Touristic Enters. Co. v. Trane, Inc.,* No. CIVA 09-02732 (SRC), 2009 WL 3818087, at *1 (D.N.J. Nov. 13, 2009) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)); *see also Phillips v. Cnty. of Allegheny*, 515 F. 3d 224, 234 (3d Cir. 2008) (relying on *Twombly* to hold that to survive a motion to dismiss a complaint must assert "enough facts to raise a reasonable expectation [] discovery will reveal evidence of the necessary element").

The Third Circuit observed, applying *Twombly* and *Iqbal*, that in evaluating the legal sufficiency of a complaint's allegations, a court "accept[s] all factual allegations as true, construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F. 3d at 233 (quoting *Pinker v. Roche Holdings Ltd.*, 292 F. 3d 361, 374 n.7 (3d Cir. 2002)). "The Court's role is not to determine whether the non-moving party 'will ultimately prevail' but whether that party is 'entitled to offer evidence to support the claims.'" *Williams v. Hospice,* No. CV-16-2095, 2016 WL 4149987, at *3 (D.N.J. Aug. 3, 2016) (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011)).

The Court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64. Moreover, "[i]n deciding a Rule

12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of the public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (emphasis added).

Additionally, F.R.C.P. Rule 15(a) declares that leave to amend "shall be freely given when justice so requires." "[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 245 (citing *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004)).

As developed below, the Complaint states allegations that give rise to a plausible, not merely possible, entitlement to relief. Plaintiff's allegations are not threadbare recitals of the elements of a cause of action but instead, provide more than sufficient detail for the Defendants to have notice of the claims against them.

V. ARGUMENT

A. Ms. Seifried's Claims are Sufficiently Pled under Both Alabama and New Jersey Law

1. Plaintiff Specifies the Extent and Roles of Each Defendant's Wrongdoing

Janssen, as a wholly owned subsidiary of J&J, "marketed, advertised, distributed, and sold" Invokana in addition to "researching, developing, designing, licensing, manufacturing, [and] supplying" it. Compl. ¶¶ 8, 14. J&J too was directly involved in such "researching, developing, designing, licensing, manufacturing, distributing, supplying, selling[,] marketing, and introducing [of Invokana] into interstate commerce." *Id.* ¶ 9. Defendants, however, aver to this Court that J&J is a mere "holding company and did not design, manufacture or sell Invokana." Def. Mot. at 5. Defendants artfully avoid Plaintiff's other allegations (which this Court must accept as true) – that J&J also partook in the "researching … developing, and

introducing [of Invokana] into interstate commerce." Compl. ¶ 9. Defendants do not dispute these roles, nor can they.

Defendants emphasize the fact that Janssen is the company that manufactures Invokana in Puerto Rico. Publicly-available documents, judicially noticeable by this Court,[2] accessed from FDA and on J&J's own website, verifies J&J's involvement in the labeling, product launch, and marketing of Invokana. Thus, even absent further discovery, based on the following, there is no question that J&J was involved in the product alleged to cause Ms. Seifried's injuries.

J&J posted an online article entitled "Behind the Product Labels."[3] The article details how a third-party label manufacturer is **"**a true partner ***for Johnson & Johnson"*** because the label manufacturer produced Invokana bottle labels in anticipation of FDA approval yet stood at the ready over the Easter holiday to change the label – at ***J&J's*** direction – in the event of "a

[2] For the same reasons that Defendants cite that this Court make take judicial notice of FDA documents, this court may do the same of the FDA documents cited herein. *See* Def. Mot. at 5, n.6; *see also Horne v. Novartis Pharms. Corp*., 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("The Court may take judicial notice of and consider the public record of the FDA . . . .").

Similarly, the Defendants' own website may be judicially noticed. *See O'Toole v. Northrop Grumman Corp*., 499 F.3d 1218 (10th Cir. 2007) (holding that the district court had abused its discretion in refusing to take judicial notice of information from the defendant's website under Rule 201); *see also Hendrickson v. eBay, Inc*., 165 F. Supp. 2d 1082, 1084 (C.D. Cal. 2001) (same); *Under a Foot Plant, Co. v. Exterior Design, Inc.,* No. 6:14-CV-01371-AA, 2015 WL 1401697, at *2 (D. Or. Mar. 24, 2015) (taking judicial notice of an archived version of the defendant's website).

The Court may accept the facts contained on Defendants' own website for the truth of the matter asserted therein. "For purposes of a 12(b)(6) motion to dismiss, a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Doron Precision Sys., Inc. v. FAAC, Inc*., 423 F. Supp. 2d 173, 179 n.8 (S.D.N.Y. 2006); *accord Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (taking judicial notice of printouts of the defendant's own website because defendant did "not actually dispute the factual material reflected in [them]," but rather "simply . . . prefer[red] that the Court not consider [them]").

[3] Exhibit A, Behind the Product Labels, *available at* https://www.jnj.com/sites/default/files/pdf/JJ%20Diversity%20--%20National%20Label%20and%20Cardinal%20--%2012-23-14.pdf.

potential request from the FDA for changes to the label." *Id.* J&J's Director of Trade Accounts is quoted as the person "who manages the relationship between [the third-party label manufacturer] **and Johnson and Johnson** and [who] over saw the product [Invokana's] launch."[4]

J&J's own website also posted (and continues to host) a "Media Fact Sheet" about Invokana, detailing in more generic terms understandable to the public at large about the drug's mechanism of action.[5]

Moreover, even though J&J attempts to establish itself as a mere holding company through its financial filings (*see* Def. Mot. at n.5), other financial filings on J&J's own website further point to the importance of Invokana to J&J's bottom line. For example, J&J's 2012 Annual report exclaimed that "**We [J&J]** have an exciting and late-stage pipeline of differentiated medicines. New Drug Applications are presently under review in the United States and in the European Union seeking approval for INVOKANA (canagliflozin), **our [J&J's]** first pharmaceutical treatment for patients with type 2 diabetes."[6] Thus, to the extent J&J attempts to shield itself from liability, by creating a set of nested Russian dolls, J&J is nevertheless at the top of the stack and directly involved, understandably, in the affairs of its underlings.[7] To wit, J&J's 2015 Annual Report states that:

---

[4] *Id.* (emphasis added).

[5] Exhibit B, Media Fact Sheet, *available at* https://www.jnj.com/sites/default/files/pdf/Janssen_INVOKANA%20FactSheet.pdf.

[6] Exhibit C, J&J's 2012 Annual Report at 7, *available at* https://www.jnj.com/sites/default/files/pdf/JNJ2012annualreport.pdf (emphasis added).

[7] Exhibit D, *see* 2015 First Quarter Report of Drug Quarter-over-Quarter sales, *available at* http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson-First-Quarter-2015-Financial-Charts.pdf (listing Invokana).

> The **Executive Committee of Johnson & Johnson is the principal management group** responsible for the strategic operations and allocation of the resources of the Company. This Committee **oversees and coordinates the activities of the Company's three business segments**: Consumer, **Pharmaceutical** and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies.[8]

J&J describes Invokana as one of the products in its Pharmaceutical segment in its 2015 Annual Report.[9] Indeed, J&J was involved with Invokana from its initial NDA application. Administrative documents & correspondence for the drug approval package for Invokana establishes J&J's role in the submission of Invokana for the FDA's approval.[10] As part of the NDA application, all FDA investigators had to reveal any financial conflicts of interest. For Invokana, a minimum of thirteen FDA investigators received (and were forced to disclose) various consulting fees ***from J&J*** (not Janssen).[11]

Moreover, Brandon Porter is listed as the Associate Director, Regulatory Affairs, for Janssen Research & Development on the NDA-related correspondence. Brandon Porter, however, wears two hats. He was simultaneously (and remains as) the Associate Director of Global Regulatory Affairs *for J&J* and, while at J&J, was a "[m]ember of the canagliflozin

---

[8] Exhibit E, J&J 2015 Annual Report, *available at* http://files.shareholder.com/downloads/JNJ/1709744668x0x881109/474857DD-8E67-43B1-BB38-0A9712D93545/2015_annual_report_.pdf, at 1 (emphasis added).

[9] *Id.* at 2.

[10] All FDA drug approval package documents are *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000TOC.cfm.

[11] Exhibit F, FDA Medial Reviews at 23, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf.

regulatory team that gained FDA approval of Invokana."[12] Similarly, Leslie Schaefer, a consumer brand director at *J&J*, is the director of marketing for Invokana.[13]

In sum, Janssen and J&J are not haphazardly "lumped together." Johnson & Johnson has a special role on the development and marketing of Invokana in its supervision of Janssen's business.[14] *See BK Trucking Co. v. PACCAR, Inc.*, No. CV 15-2282 (JBS/AMD), 2016 WL 3566723, at *6 (D.N.J. June 30, 2016) (naming defendants together in one action was allowed because "Plaintiffs have alleged that all defects requiring repair [when the specific] component systems is uniquely within Defendants' control. The Court cannot expect Plaintiffs to provide more specificity about the [component] without the benefit of discovery.").

2. Ms. Seifried's claims are plausibly pled under Alabama law

As explained below, Ms. Seifried's claims are plausibly pled under Alabama law. The Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") is "a judicially created accommodation of Alabama law to the doctrine of strict liability for damage or injuries caused by allegedly defective products." *Wyeth v. Weeks*, 159 So. 3d 649, 656 (Ala. 2014). The

---

[12] Exhibit G, FDA Administrative Documents & Correspondence at 88, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000Admincorres.pdf; *see also* Exhibit H, LinkedIn, Brandon Porter, *available at:* https://www.linkedin.com/in/brandon-porter-3aa46a.

[13] Exhibit I, LinkedIn, Leslie Schaefer, *available at* https://www.linkedin.com/in/leslieschaefer66bb744.

[14] For example, many of the top leadership of J&J wear two hats and sit on leadership team of Janssen as well. As a few examples, Joaquin Duato is the Executive Vice President and Worldwide Chairman, Pharmaceuticals for Johnson & Johnson, but also is listed as part of Janssen's leadership. *See* "Our Leadership, Janssen," *available at* http://www.janssen.com/about/our-leadership. The same is true for Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Pharmaceuticals; Dr. William Hait, Global Head, Research & Development; Patrick Verheyen, Global Head of Business Development; and Linda Fedow, Global Lead, Pharmaceuticals Communication & Public Affairs. *Id.*

AEMLD did not subsume a common-law negligence or wantonness claim. *Id.* To establish liability under the AEMLD, a plaintiff must show:

> [1] that an injury was caused by one who sold a product in a defective condition that made the product *unreasonably dangerous* to the ultimate user or consumer; [2] that the seller was engaged in the business of selling such a product; and [3] that the product was expected to, and did, reach the user without substantial change in the condition in which it was sold.

Bell v. T.R. Miller Mill Co., 768 So. 2d 953, 957 (Ala. 2000) (emphasis added); *see also Grimes v. General Motors Corp.*, 205 F. Supp. 2d 1292, 1294 (M.D. Ala. 2002); *Hicks v. Commercial Union Ins. Co.*, 652 So. 2d 211, 215 (Ala. 1994).

Ms. Seifried has satisfied these preliminary elements for every form of her product liability claims (manufacturing defect, design defect, and failure to warn). *First*, she was injured. Compl. ¶ 4 ("After beginning treatment with INVOKANA … Plaintiff developed diabetic ketoacidosis."). *Second*, Plaintiff pled that Invokana is unreasonably dangerous. *See* Compl. ¶¶ 19-24 (explaining the increased dangers of SGLT2 diabetes drugs over non-SGLT2 drugs—including and especially Invokana – in light of mounting FDA adverse event reports). *Third*, Defendants are in the business of selling Invokana. *See* Compl. ¶¶ 8-10. *Fourth*, the Invokana prescribed and consumed by Ms. Seifried was in the same condition in which it was sold, and was unaltered. Compl. ¶ 29. Plaintiff's claims are plausible and give appropriate notice to Defendants.

a. Manufacturing Defect (Count 1)

Under the AEMLD, a manufacturer has the duty to design and manufacture a product that is reasonably safe for its intended purposes and uses. *Casrell v. Altec Industries, Inc.*, 335 So.2d 128 (Ala. 1976); *Atkins v. American Motors Corp.*, 335 So. 2d 134 (Ala. 1976). In addition to the preliminary product liability elements discussed above, a manufacturing defect claim under

Alabama law is an allegation that a particular product was defectively manufactured. Plaintiff has so alleged. Specifically, Ms. Seifried alleges that the Invokana she consumed deviated from the "performance standards" that J&J and Janssen both set for "otherwise identical units [of Invokana pills] manufactured to the same manufacturing specifications or formulae." Compl. ¶ 46; *see also id.* ¶ 45.

Defendants contend that "Courts in two other Invokana cases have dismissed virtually identical manufacturing defect claims as insufficiently pled." Def. Mot. at 8. Neither of these cases are Alabama cases, and Defendant provides no further discussion of the manufacturing allegations in those complaints.

Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims, like this one (subject to "plausibility"). Plaintiff need not show, at this stage, "how" J&J and Janssen's manufacturing defect caused her injuries and "how" the Invokana pills consumed by Ms. Seifried were different than its intended design. Def Mot. at 7. To require such facts at this stage would be akin to requiring an expert report filed with the complaint. No holding has ever gone so far.

b. Design Defect (Count 2)

As noted, Under the AEMLD, a manufacturer has the duty to design and manufacture a product that is reasonably safe for its intended purposes and uses. *Casrell v. Altec Industries, Inc.*, 335 So. 2d 128 (Ala. 1976); *Atkins v. American Motors Corp.*, 335 So. 2d 134 (Ala. 1976). Further, the AEMLD requires a safer, practical alternative design. *General Motors Corp. v. Edwards*, 482 So. 2d 1176, 1191 (Ala. 1985), overruled on other grounds, *Schwarz v. Volvo N. America Corp.*, 554 So. 2d 927 (Ala. 1989).

Plaintiff's design defect claim satisfies the Rule 12(b)(6) standard, because she alleges each element of a design defect claim under the AEMLD. Although Defendant argues to the

contrary, Plaintiff alleges a defect in the design of Invokana, that is, that the drug caused her a permanent physical injury of diabetic ketoacidosis, Compl. § 51. Plaintiff further alleges that the defect proximately caused the harm for which recovery is sought. Compl. § 41. Finally, Plaintiff alleges that a feasible design alternative existed that would have to a reasonable probability prevented the harm. Compl. § 52. Because Plaintiff has satisfactorily alleged a design defect claim under Alabama law, Defendant's motion to dismiss should be denied on this ground. *See, e.g., Houston v. Bayer Healthcare Pharmaceuticals, Inc.*, 16 F. Supp. 3d 1341, 1348 (N.D. Ala. 2014) (design defect claim properly pled where Plaintiff identifies "crucial defect" of the product).

Again, Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims. Plaintiff need not support her complaint with expert testimony as to complicated matters at this stage of the litigation. According to Defendants, Plaintiff must present – in their complaint – an expert report on how SGLT2 inhibitors, and Invokana specifically, increase the risk of diabetic ketoacidosis. It is unclear how such a presentation would be done absent an expert report. So long as the litigation proceeds and Plaintiff's expert's theory is viable, it is the trier of fact who is to decide whether J&J and Janssen's design was reasonable.

Defendants' citations to *Fleming v. Janssen Pharmaceuticals*, No. 2:15-cv-02799, 2016 WL 3180299 (W.D. Tenn. May 6, 2016), *Guidry* and *Brazil* do not warrant dismissal of this claim. These were different complaints, from different jurisdictions, filed by different plaintiffs, and deficiencies that the courts found in them are not present in Mr. Swinney's complaint.

c. Failure-to-Warn (Count 3)

A drug manufacturer must provide adequate warnings about the dangers of its product to avoid liability under the AEMLD. *See, e.g., Stone v Smith, Kline, & French Laboratories*, 447

So. 2d 1301, 1304 (Ala. 1984). Plaintiff's failure to warn claim is simple: Ms. Seifried suffered diabetic ketoacidosis and that Defendants failed to adequately warn the medical community, including her physician, about such risks. Compl. ¶ 4; ¶ 54. There is no disconnect between the failure to warn claim and the injuries Ms. Seifried suffered as Defendants contend. Def. Mot. at 10.

Notably, Defendants fail to acknowledge that in May of this year, the FDA required Defendants to *strengthen* the warnings for Invokana. Specifically, the FDA requested new precautions under two of the six safety labeling sections for Invokana.[15] Among those changes was an added section under "WARNINGS AND PRECAUTIONS" for "Ketoacidosis," including "Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization have been identified in patients … receiving sodium glucose co-transporter-2 (SGLT2) inhibitors, including INVOKANA."[16] The same revised warnings included the fact that "in many of the postmarketing reports … the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed…." Doctors are now instructed that [b]efore initiating INVOKANA, consider factors in the patient history that may predispose to ketoacidosis." *Id.* Further, in June of this year, the FDA released an over-arching "Safety Announcement" applicable to Invokana.[17] This information, and these warnings, were not

[15] *See* Exhibit K, FDA May 2016, Drug Safety Labeling Changes, *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm505586.htm.

[16] *See* Exhibit L, FDA Invokana warning changes over Time, *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).

[17] *See* Exhibit M, Invokana Safety Announcement, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM506772.pdf and Exhibit N http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm506554.htm (similar).

available to Plaintiff's physician before Invokana was prescribed.[18] It therefore makes no sense for Defendants to claim that Plaintiffs' failure to warn claim is not plausible when the current label, although not the one in effect when he used the product, contains a warning for the very injury he suffered. There was no warning of diabetic ketoacidosis on the label in effect in 2015. These are questions of fact for a jury, not to be resolved as a matter of law on a motion to dismiss. *See, e.g.*, *Yamaha Motor Co. v. Thornton*, 579 So. 2d 619, 621 (1991) (The question whether a product is "unreasonably dangerous" is for the trier of fact, just as a question of negligence is.").

Defendant contends that "Plaintiff's claim fails to the extent it is based on a failure to warn about a risk of kidney damage, stroke, and heart attack." Def. Mot. at 10. But these risks, and what and when Defendant knew about them, shed light on Defendants' conduct, their pharmacovigilance program, and notice that their product was hazardous and accompanied by an inadequate warning. Defendant then asserts that Plaintiff alleges no facts to support a reasonable inference that Defendants knew or should have known about the risk of diabetic ketoacidosis. *Id*. at 11. This argument fails as Defendant acknowledges Plaintiff's allegation that the FDA had indeed received "a significant number of reports of diabetic ketoacidosis." *Id.*

Defendants' argument ignores the Rule 8 plausibility standard and points out alleged gaps in Plaintiff's allegations, *see* Def. Mot. at 12-13. On a motion to dismiss, the Court must accept these facts as true. Defendants further attack the use of adverse event reports, *see* Def. Mot. at 13, and state that "such reports do not and cannot establish causation." Of course, at this stage of

[18] *Compare* Exhibit J, 2013 Invokana warnings, *available at* http://www.accessdata.fda.gov/drugsatfda_dsssocs/label/2013/204042s000lbl.pdf (no diabetic ketoacidosis warning) *to* Exhibit O, Revised May 2016 Invokana Warnings, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf (diabetic ketoacidosis warning added).

the litigation, Plaintiff has no requirement to establish causation. *See, e.g., Rhoton v. 3M Co.*, No. 2:15-cv-1306, 2015 WL 7770234, at *2 (N.D. Ala. Dec. 3, 2015) (causation properly left to summary judgment or jury).

The citation to *Fleming v. Janssen Pharmaceuticals*, No. 2:15-cv-02799, 2016 WL 3180299 (W.D. Tenn. May 6, 2016) is unavailing. In *Fleming*, the court specifically found that Plaintiffs' allegations "made only conclusory statements as to the failure of Defendants to warn about the dangers of Invokana. *Id*. at *7. That is not the case here.

d. Warranty Claims (Counts 4, 5, and 7)

1. Express Warranty

Ala. Code § 6-5-521(a) provides for a warranty, "[i]f it becomes part of the basis of the bargain: (1) any affirmation of fact or promise that relates to the goods creates an express warranty that the goods shall conform to the affirmation or promise; (2) any description of the goods creates an express warranty that the goods shall conform to the description; and (3) any sample or model creates an express warranty that the goods shall conform to the sample or model." Ala. Code § 7-2-313(1). Formal words like "warrant" or "guarantee" are not required. Ala. Code 7-2-313(2). Thus, under the Alabama Commercial Code, an express warranty is created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain [or] [a]ny description of the goods which is made part of the basis of the bargain." Ala. Code § 7–2–313; *Rhoton v. 3M Co*., No. 2:15-cv-1306, 2015 WL 7770234, at *2 (N.D. Ala. Dec. 3, 2015).

Here, it is undisputed (or, at a minimum, plausibly alleged in the complaint or through judicially-noticeable facts discussed above) that: 1) Invokana was safe and fit for its intended

purposes through Defendant's statements as of Ms. Seifried's ingestion in 2014,[19] and 2) that the description of Invokana was not safe because it has serious side effects, namely the one suffered by Ms. Seifried: diabetic ketoacidosis.[20]

2. Implied Warranty

Implied warranties are covered by the Alabama Commercial Code. Under § 7–2–314(1), "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Under § 7–2–314(2)(c), "goods to be merchantable must be at least such as ... [a]re fit for the ordinary purposes for which such goods are used." *Houston v. Bayer Healthcare Pharmaceuticals*, 16 F. Supp. 3d 1341, 1345-46 (N.D. Ala. 2014).

Here, Ms. Seifried has made the requisite allegations. She alleges that she consumed Invokana pills for the purpose for which Defendants intended: long term treatment of her diabetes. Compl. ¶¶ 28-29. She alleges that Defendants knew of the use for which Invokana was intended (treatment of diabetes). Compl. ¶¶ 95, 97. And Plaintiff alleges that Defendants were aware that consumers, including Ms. Seifried, would use Invokana for treatment of type 2 diabetes (a life-long disease) and other purposes such as weight loss and reduced blood pressure. Compl. ¶¶ 96-98, 103.

e. Negligence-based Claims (Counts 6 and 9)

Defendants merely argue that because Plaintiff's product-liability-based claims must fail

---

[19] Compl. ¶ 66; *see also* Exhibit P, Defendants' Invokana website as of June 13, 2014, *available at* https://web.archive.org/web/20140613010318/http://www.invokana.com/about-invokana/what-is-invokana (stating that "It's the first of a new kind of prescription medicine that's proven to significantly lower blood sugar (A1C)", but containing ***no*** warnings under "IMPORTANT SAFETY INFORMATION" as to renal/kidney damage).

[20] *See id.*; *see also* Compl. ¶ 67.

(Count 1 [Manufacturing Defect], 2 [Design Defect], and 3 [Failure-to-Warn]), Plaintiff's negligence-based claims (Counts 6 & 9) must fail too. For the same reasons discussed above, those claims are plausibly pled and survive.

f. Fraud-based claims (Counts 8–11)

In Alabama, a drug manufacturer "may be held liable for fraud or misrepresentation (by misstatement or omission)" based on "information and warning deficiencies" on a drug's labelling. *Wyeth, Inc. v. Weeks,* 159 So. 3d 649, 676 (Ala. 2014). A fraudulent-misrepresentation action is governed by § 6–5–101, which provides that "[m]isrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud." A claim of fraudulent misrepresentation comprises the following elements: "(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." *Fisher v. Comer Plantation*, 772 So. 2d 455, 463 (Ala. 2000) (quoting *Baker v. Bennett,* 603 So. 2d 928, 935 (Ala.1992)). Negligent Misrepresentation is similar and overlaps to a large degree.

"Like the *Iqbal* standard, this is not a hard-and-fast test, but can vary based on the nature of the claim asserted." *Houston v. Bayer Pharmaceuticals, Inc.*, 16 F. Supp. 3d 1341, 1349 (N.D. Ala.). An "overly rigid view of the [Rule 9] formulation" is not appropriate. *Id.* at 1350. Instead, defendants "may be held liable for fraud or misrepresentation (by misstatement or omission) based on information and warning deficiencies on a drug's labeling." *Id*. (citation omitted).

In *Rhoton v. 3M Co*., No. 2:15-cv-1306, 2015 WL 7770234 (N.D. Ala. 2015), Plaintiffs adequately alleged "reliance through their physician, a learned-intermediary, who relied upon defendants' representations 'through the labeling, advertising, marketing materials, seminar

presentations, publications, notice letters, and regulatory submissions.'" *Id*. at *3. The *Rhoton* Court further noted that "[t]hese medical device and drug manufacturer cases also often involve 'FDA approval requirements' whereby a plaintiff can 'base her fraud and misrepresentation claims on the defendant manufacturer's breach of its duty to warn about the risks associated with the long-term use of the drug in its labeling.'" *Id*., citing *Houston*, 16 F. Supp. 3d at 1350.

The *Houston* court found that Plaintiff had stated a claim of this kind with the "particularity" required by Rule 9. As to the "precise statements" requirement and the "time, place, person" requirement, Plaintiff alleged that the product, Mirena, came with a package label that warned about certain dangers. *Houston*, 16 F. Supp. 3d at 1350. As to the "content and manner in which the statements misled" requirement, Plaintiff alleged that defendant "owed a duty to provide accurate and complete information regarding Mirena" on this labeling, and that it breached this duty by failing to warn about an increased risk of injury. *Id*. As to the "what defendants gained" requirement, she has alleged that this breach of duty induced plaintiff to use the Mirena device." *Id.*

Defendants do not contest Plaintiff's causation or losses allegations. Instead, Defendants only claim that Plaintiff's "who, what, when, where, and why" claims are insufficient. Def. Mot. at 15. Defendants' chief complaint is that Plaintiff's failed to point to – among thousands of such examples – marketing materials about Invokana contained material facts about safety. Def. Mot. at 15 n.17. But the court may consider all of the materials that Plaintiff has already pointed to as judicially noticeable for this reason – for the same reason that Defendants have pointed to their external materials for consideration. *See* Section V.A.1. Each one of those (specifically-dated) statements made by each of the Defendants (or in concert) list who made them, and how they made them (in which medium). *See id.* The why is simple: "sales and profits at the expense of the health and safety of the public." Compl. ¶ 173.

For example, Defendants' media fact sheet, attached as Exhibit B, omits material safety information about Invokana. "Fraud by omission ... is by its very nature, difficult to plead with particularity." *Dineen v. Pella Corp*., 2015 WL 6688040, at *10 (D.S.C. Oct. 30, 2015).

Who:	Janssen and J&J.
What:	Defendants "omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public." Compl. ¶ 138(b). Namely, nowhere in the 2013 label do the Defendants disclose the risks of diabetic ketoacidosis. It was not until the 2016 label that Defendants disclosed any such risk. Exhibit O.
When:	March 2013 (date on page 41 of Ex. O).
Where:	In product boxes, disseminated to treating doctors and to the public at large.
How:	By misleading prescribing doctors and the public at large as to the relative safety of Invokana when compared to other similar diabetic medications. *See also* Compl. ¶¶ 116, 120-123, 137. 150.
Why:	"[S]ales and profits at the expense of the health and safety of the public." Compl. ¶ 173.

3. There is No Basis for Striking any of Plaintiff's New Jersey Claims

a. It is too early to determine if Plaintiff's implied warranty, negligence-based, and fraud-based claims (Counts 5–11) are subsumed by the New Jersey Product Liability Act

Although the Court may determine that certain claims are subsumed by the NJPLA at a later time, it is premature to make this determination at this phase absent a choice of law analysis. Defendants have made no meaningful effort to do so and Plaintiff agrees that on a motion to dismiss, it is inappropriate to do so. [21]

b. The manufacturing defect (Count 1) is plausibly pled under the NJPLA

Under New Jersey law, a manufacturing defect is a deviation "from the design specifications, formulae, or performance standards of the manufacturer or from otherwise

[21] *See* Section III (discussing that is premature to make a finding on a choice of law on a motion to dismiss); *see also ADP, LLC v. Bakshi*, No. CV 15-8385 (CCC), 2016 WL 1223557, at *6 (D.N.J. Mar. 29, 2016) ("[D]isputes require discovery and further exploration before a proper choice of law analysis can be performed.").

identical units manufactured to the same manufacturing specifications or formulae." *Myrlak v. Port Authority of N.Y. and N.J.*, 157 N.J. 84, 96 (1999) (quoting N.J.S.A. 2A:58C–2a). It occurs when the "product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing specifications." As discussed, *see* Section V.A.2.a, Plaintiff has so alleged. Compl. ¶¶ 46-47.

Importantly, "[t]he Supreme Court of New Jersey has held that the plaintiff may show the [manufacturing] defect through expert testimony or circumstantial evidence." *Ebenhoech v. Koppers Indus., Inc.*, 239 F. Supp. 2d 455, 472 (D.N.J. 2002) (citing *Myrlak*, 157 N.J. at 97). In such a scenario, "proof of proper use, handling, or operation of the product and the nature of the malfunction, may be enough to satisfy the requirement that something was wrong with it. Further, a defective condition can also be proven by the testimony of an expert." *Ebenhoech v. Koppers Indus., Inc*., 239 F. Supp. 2d 455, 472 (D.N.J. 2002). But Defendants' handling and packaging of Invokana is necessarily only in the knowledge of the defendants that discovery will reveal. Thus it is appropriate to withhold dismissal of this claim under New Jersey law given the broad scope of a manufacturing defect claim's proof.[22]

c. The design defect (Count 2) is plausibly pled under the NJPLA

Defendants insist that plaintiff must show a reasonable alternative design and "facts" to support that a reasonable alternative design is feasible. Under New Jersey law,

> "[a] plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an

[22] Moreover, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Alabama law. Thus, for the same reasons as stated above, Plaintiff need not prove her case in her complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was manufactured at this stage of the litigation. All plaintiff must do is allege facts that make it plausible that it is the case. Plaintiff has done so for the same reasons stated in Section V.A.2.a., *supra*.

> alternative manner so as to minimize or eliminate the risk of harm. Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible."

Schraeder v. Demilec (USA) LLC, No. CIV. 12-6074 FSH, 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (citing *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570–71 (NJ 1998)).

These elements of proof at trial, however, are not required to be proven at the pleading stage. An alternative design need not be pled because "it is not required that the Plaintiffs always plead a reasonable alternative design." *Id.* "A plaintiff must prove ***either*** that the product's risks outweighed its utility ***or*** that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Am. Cyanamid Co.*, 155 N.J. at 570–71 (emphasis in the original). Thus, it is almost always that "the jury [i]s required to perform a risk-utility analysis." *Lewis v. Am. Cyanamid Co*., 155 N.J. at 560. And a jury's evaluation of the risk-utility factors "may justify a conclusion that ***even though there is presently no alternative design*** which would make a product safer [liability may still be found]." *Smith v. Keller Ladder Co*., 275 N.J. Super. 280, 283-84 (N.J. App. Div. 1994) (emphasis added).

Even though not required under New Jersey law, as discussed, *see* Section V.A.2.b., *supra*, Plaintiffs have pointed to such a feasible alternative design: the existence of "alternative safer products" when compared against Invokana, which is "more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes." Comp. ¶¶ 25, 51(b), (c).[23]

[23] Again, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Alabama law. Thus, for the same reasons as stated above, Plaintiff need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was designed at this stage of the litigation. All Plaintiff must do is allege facts that make it plausible that it is the case. Plaintiff has done so for the same reasons stated in Section V.A.2.b., *supra*.

But it is not only the existence of safer, alternative type 2 diabetes medications that form the basis for a design defect, it is also the insufficient and inadequately tested and labeled Invokana. Comp. ¶¶ 51(d) & (f). Defendants do not attempt to refute these allegations.

d. The failure to warn claim (Count 3) is plausibly pled under the NJPLA

As noted at Section V.A.2.c., *supra*, weighing the adequacy of Defendants' warnings is not appropriate on a motion to dismiss. This is equally as true under New Jersey law as Alabama law. *See In re Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litig.*, No. CIV. 12-711, 2014 WL 3971620, at *6 (D.N.J. Aug. 13, 2014) ("In ruling on a motion to dismiss, the Court may not weigh evidence or otherwise decide which version of the facts is true.") (citing *Acevedo v. Monsignor Donovan High Sc*h., 420 F.Supp.2d 337, 342 (D.N.J.2006)). Countless New Jersey Courts have held the same in the context of pharmaceutical cases. *See, e.g., In re Reglan Litig.*, No. A-2014-13T4, 2014 WL 5840281, at *7 (N.J. Super. Ct. App. Div. Nov. 12, 2014), leave to *appeal granted*, 224 N.J. 278 (App. Div. 2015); *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 197 (N.J. 2012). Thus, for the same reasons stated in Section V.A.2.c., *supra*, this Court should not dismiss Plaintiff's failure to warn claim.

e. Ms. Seifried's express warranty claim (Count 4) is plausibly pled

Defendants argue that plaintiff failed to provide a pre-suit notice under New Jersey law of her express warranty claim. But because it is premature to determine if Plaintiff's express warranty claim should be analyzed under Alabama or New Jersey law (and because Defendants have made no attempt, as is their burden, to argue which should apply) the question of pre-suit notice under New Jersey Law (if even applicable) is premature. *See* Section III.

Defendants' remaining quarrels with Plaintiff's express warranty claim are the same as those outlined as to the Alabama claim: they want "more." But for the same reasons that

Plaintiff's express warranty claim would survive under Alabama law, it survives under New Jersey law. *See* Section V.A.2.d.1.

4. Ms. Seifried's Claim for Punitive Damages (Count 12) Survives

Generally, New Jersey allows for punitive damages in cases where "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's [FDA's] regulations, which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C-5c. As Defendants point out, however, following *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but, importantly, before *Wyeth v. Levine*, 555 U.S. 555, the New Jersey appellate decision held that punitive damages could not be sought under the facts of *McDarby v. Merck & Co*., 949 A.2d 223, 275–76 (N.J. Super. Ct. App. Div. 2008). *Wyeth* held that federal law does not preempt state torts claims imposing liability on drug labeling that the FDA had previously approved because FDA's "changes being effected" (CBE) regulation permits unilateral labeling changes that improve drug safety. 555 U.S. at 568 (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). As such, the Supreme Court stated, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." 555 U.S. 555, 570–71. Thus, subsequent to *Wyeth*, this District and other districts across the nation have called *McDarby's* reasoning into question. "The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth*." *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009). "The holding of *McDarby*, however, has been called into doubt by *Wyeth* … and *Forman v. Novartis Pharmaceuticals Corp*., 793 F.Supp.2d 598 (E.D.N.Y. 2011)." *Hill v. Novartis Pharm. Corp.*, No. 1:06-CV-00939-AWI, 2012 WL 967577, at *2 (E.D. Cal. Mar. 21, 2012) (same).

Timing is critical. Because *McDarby* preceded *Wyeth*, the *McDarby* court did not have the ability to consider the Supreme Court's determination that a drug manufacturer may change

the label of brand-name drugs without prior FDA approval for reasons of safety. Thus, it is possible for a drug manufacturer to come to know of information that would call for an updated warning (*i.e.*, knowingly withhold information from the FDA), but fail to update the labeling, thereby satisfying N.J. Stat. Ann. § 2A:58C-5c.

With respect to Alabama, Defendants only quarrel that punitive damages are a remedy, not a cause of action. But they have not stated, at all, why Plaintiff should not be able to pursue such punitive damage as a matter of law given that Plaintiffs *have* included punitive damages in their prayer for relief. Compl. at 40. Thus, any determination on punitive damages under Alabama law is premature because Plaintiff has done exactly what Defendants demand: prayed for such relief. Ala. Code § 6-11-20;[24] *Rhoton v. 3M Co.*, No. 2:15-cv-1306, 2015 WL 7770234, at *4 (N.D. Ala. Dec. 3, 2015).

B. Ms. Seifried's Design Defect-Based Claims Are Not Preempted By Federal Law

Invokana is a brand-name prescription drug for which there is currently no generic equivalent. Generally speaking, brand-name prescription drugs are regulated differently than generic prescription drugs. This is because it is the brand-name manufacturer that seeks approval from the FDA to market the drug and which is in possession of clinical testing data and safety information, conducted and collected both before and after a drug comes to market. By contrast, generic manufacturers do not generally conduct safety testing. Rather they are merely copying an existing formulation for a brand name drug. Indeed, that is why generic manufacturers must conform their product labels with those of the brand name manufacturers. 57 Fed. Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug

[24] Ala. Code § 6-11-20(a) provides: Punitive damages may not be awarded in any civil action, except civil actions for wrongful death pursuant to Sections 6-5-391 and 6-5-410, other than in a tort action where it is proven by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff.

product's labeling because the listed drug product is the basis for [generic drug] approval"). Courts have recognized this distinction and have generally ruled that state claims for failure to warn (and in some cases, design defect) against *generic* manufacturers are preempted. *See, e.g.*, *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (dismissing all generic propoxyphene cases in a MDL). Courts, however, have not typically extended this protection to brand name prescription drug manufacturers.

Despite the Supreme Court precedent recognizing this distinction, Defendants argue that their *brand*-name drug should still be protected from liability under a theory of *conflict* preemption theory because it is the FDA, not the Defendants, that approved its drug design, composition, and dosage. Def. Mot. at 21-27. While that may be true, it is the Defendants that submitted their drug for approval in the first instance. It is the Defendants that initially designed and developed Invokana, and submitted proposed labeling for the drug. Therein lies Defendants' liability. Further, absent discovery regarding the regulatory submissions made by Defendants, as well as any communications between Defendants and the FDA, it is not what information was provided to the FDA regarding the safety of the drug. Thus, as a practical matter, any consideration of conflict preemption would be premature.

Nevertheless, Defendants cite to three Supreme Court cases that they claim require dismissal with prejudice. None of the three Supreme Court cases Defendants cite, as discussed below, at issue are on point, and certainly none of them mandate dismissal of Plaintiff's claims.

First, *Wyeth* held that a brand-name drug manufacturer can be held liable for failure to warn claims because regulations allow a manufacturer to implement label changes with the FDA's prior approval. Thus, the Court stated:

> Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case . . . . We conclude that it is not impossible for Wyeth to comply with its state-and federal-law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.

Wyeth v. Levine, 555 U.S. 555, 581 (2009).

The second case cited by Defendants, the *Mensing* case, reiterates *Wyeth* but instead does preempt failure-to-warn claims when a ***generic***, and not brand-name, drug is at issue.

> We recognize that from the perspective of [plaintiffs] Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, *substituted generic metoclopramide* instead, federal law pre-empts these lawsuits.

PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) (emphasis added). The Plaintiff in this case took brand name Invokana, not a generic substitute—because no such generic drug exists. Compl. ¶ 8.

Finally, the third case cited by the Defendants, *Bartlett*, simply extended *Mensing* such that claims involving ***generic*** drugs applies to design-defect claims (and not only failure to warn claims as were at issue in *Mensing*). "As *PLIVA* made clear, federal law prevents *generic drug manufacturers* from changing their labels." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) (emphasis added). Thus, these cases provide no basis for dismissal of a brand-name drug.

The Defendants cite several lower court decisions in jurisdictions not binding on this Court that extend the *Mensing* and *Bartlett* opinions beyond the realm of generic drugs – but

mostly applying preemption *outside the context of pharmaceutical drugs*. Def. Mot. at 24-25.

For example, Defendants cite to the Third Circuit case *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680 (3d Cir. 2016). That citation is odd for multiple reasons. First, *Sikkelee* held that the Federal Aviation Act of 1994 (hardly a pharmaceutical case) does *not* act to preempt state-law based aircraft product liability claims. *Id.* at *683. The Third Circuit so held because of the "presumption against preemption [under which] Congress must express its clear and manifest intent to preempt an entire field of state law." *Id.* Second, the Third Circuit expressly states the opposite of the proposition for which Defendants say it stands for.

> In a series of recent preemption cases, the [Supreme] Court has **distinguished between brand-name drugs and their generic equivalents**, determining that at least some state law tort claims may be brought against brand-name drug companies because such companies have the ability to make some unilateral changes to their labels without additional regulatory preapproval, but such claims against generic drug manufacturers cannot survive a conflict preemption analysis because the generic manufacturers are bound by federal law to directly mimic their brand-name counterparts.

Id. at *703 (emphasis added).

As the Third Circuit boiled down so well, generic drug claims of all types usually fail, but branded-name drugs (like Invokana) are not preempted. Two sister courts in this Circuit agree, of course. "The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products." *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014).

> [T]he same federal regulations that apply to generic manufacturers do not necessarily apply to brand-name manufacturers, such as the defendants. … This explains why the failure-to-warn claim brought against a generic drug manufacturer in PLIVA was preempted but failure-to-warn claim brought against the brand-

> name manufacturer in *Wyeth v. Levine* was not. … Following from this logic, I find that *Bartlett*—a case involving a generic manufacturer and following *PLIVA v. Messing*—does not apply to the plaintiff's design defect claim against a brand-name manufacturer. Under the dictates of *Wyeth v. Levine*, preemption is not warranted.

Terry v. McNeil-PPC, Inc., (In re Tylenol (Acetaminophen) Mktg.), No. 2436, 2015 WL 7075949, at *21–22 (E.D. Pa. Nov. 13, 2015).

The outlier cases cited by Defendants cannot be reconciled with the explicit language in *Mensing* and *Bartlett* and should be disregarded by the Court. As one district court noted about the rationale espoused by Defendants by the outside-of-this-circuit cases they cite, "[i]f this is the correct interpretation of *Bartlett*, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted." *Trahan v. Sandoz, Inc.*, No. 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015). Defendants' interpretation of the law of federal preemption cannot be (and is not) correct.

C. All of Ms. Seifried's Claims against Johnson & Johnson Remain Valid

As noted above, *see Section* V.A.1., *supra*, Johnson & Johnson had direct involvement in the development, sale, and marketing of Invokana. Even if this Court is not inclined to judicially notice the multitude of types and sources of materials supporting J&J's awareness of and participation in the development and marketing of Invokana, this Court should *still* allow claims against J&J to proceed at this stage in the litigation.

Plaintiff's claims allege that J&J, *inter alia*, marketed Invokana. Compl ¶ 9. Based on far less, indeed mere knowledge of a subsidiary's wrongdoing, the Northern District of Texas allowed such claims to proceed against J&J with respect to its medical device wholly-owned subsidiary, DePuy. *Lay v. DePuy Orthopaedics, Inc.* (*In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*), No. 3:11-MD-2244-K, 2014 WL 3557392 (N.D. Tex. July 18,

2014). There, the court reasoned that Restatement (Second) of Torts §876(b) applies because J&J "is subject to liability for harm to a third person resulting from the tortious conduct of another if [it] knows that the other's [here, Janssen's] conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself." *Id.* at *3. The case had already survived on a motion to dismiss on this ground and discovery revealed that the "evidence ... raises fact issues that the Johnson & Johnson Companies knew that DePuy was engaged in the manufacture and marketing of a defective product and that they provided assistance to DePuy in marketing that product." *Id.* That knowledge included, among other things, that its subsidiary was facing manufacturing problems with its hip components, which J&J continued to exercise control over marketing and advertising, that the J&J name was placed on packaging of the device, and that the J&J name was used in doctor marketing efforts. *Id.* at *3.

New Jersey recognizes the Restatement (Second) of Torts §876(b). "The Supreme Court of New Jersey adopted the Restatement (Second) of Torts § 876(b) standard." *Shah v. Wisconsin*, No. CIV. 11-0419, 2011 WL 5192127, at *5 (D.N.J. Oct. 31, 2011) (citing *Tarr v. Ciasulli*, 181 N.J. 70, 853 A.2d 921, 928 (N.J. 2004)); *see also Failla v. City of Passaic*, 146 F.3d 149, 158 (3d Cir. 1998); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 129 (3d Cir. 1999); *Bondi v. Citigroup, Inc.*, No. L-10902-04, 2005 WL 975856, at *17 (N.J. Super Ct. Law Div. Feb. 28, 2005) (stating that courts in this circuit and in New Jersey recognize "civil aiding and abetting liability" as described in the Restatement (Second) of Torts § 876(b)).

The facts alleged and/or judicially noticeable here support a claim under the Restatement (Second) of Torts §876(b). As noted above, this Court can take judicial notice of the fact that J&J: (1) directed the physical labeling of Invokana; (2) published media information about Invokana's method of action; (3) announced to its shareholders its hopes for an approval of

Invokana in 2012; (4) shared executives between J&J and Janssen; and (5) J&J's consumer brand director was (and remains) in charge of Invokana's marketing. Any one of these facts could lead a reasonable juror to believe that J&J's conduct constitutes a breach of duty and gives substantial assistance or encouragement to Janssen's conduct.

Moreover, Plaintiff's design defect does not call for the Defendant's to reformulate Invokana *now*, it is a claim that they should not have submitted the formulation (*i.e.*, its design) in the first instance for approval. In other words, it is incumbent upon the drug manufacturer to make sure the drug is safe at all times – including the time the drug is first brought to market.

V. CONCLUSION

Plaintiff's complaint meets the applicable pleading standards. As a result, Defendants' motion to dismiss should be denied in its entirety.

Respectfully submitted,

SEEGER WEISS LLP

By: /s/ Christopher A. Seeger
Christopher A. Seeger
Jeffrey Grand (*pro hac vice* pending)
Daniel R. Leathers
550 Broad Street Suite 920
Newark, New Jersey 07102
Telephone: (973) 639-9100
Facsimile: (973) 639-9393
E-mail: cseeger@seegerweiss.com
E-mail: jgrand@seegerweiss.com
E-mail: dleathers@seegerweiss.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

It is hereby certified that a true copy of the foregoing was served electronically via the Court's electronic filing system on the 15th day of August 2016, upon all counsel of record.

Dated: August 15, 2016

/s/ Christopher A. Seeger
Christopher A. Seeger